

REMARKS

Consideration of the present application, as amended, is respectfully requested.

A. STATUS OF THE CLAIMS

Claims 1 and 4-17 are pending. Claims 2-3 and 18-21 are cancelled without prejudice to further prosecution of the subject matter of the cancelled claims. The insertion of the definition of "stringent conditions" into claims 6 and 17 is supported by the specification at page 10, lines 1-18. The upper limit of percent homology is supported in the specification at page 14, lines 15-22.

B. PERFECTION OF THE PRIORITY DATE

At the last paragraph of page 2 of the Office Action, the Examiner has accepted that the present application is entitled to a priority date of October 7, 2002 based on the Japanese priority application. Applicants enclose herewith an English language translation of the Japanese priority document for the Examiner's consideration in perfecting the October 7, 2002 priority date.

C. OBJECTIONS TO THE CLAIMS ARE OBVIATED

At page 3 of the Office Action, the claims were objected to for allegedly being in improper form.

Claims 4 and 17 were objected to for being dependent from non-elected claims. Claims 4 and 17 are now in independent form, thus obviating this ground of objection.

Claim 1 was objected to for reciting "base sequences." This phrase has now been replaced by "nucleotide sequences," thus obviating this ground of objection.

Claims 11-13, and claim 1, line 27 are amended as suggested by the Examiner, thus obviating this ground of objection.

Claims 6, 7, 9, 10, 12, 13 and 15-17 are now amended to remove the noted multiple dependencies, and are now submitted to conform to the rules of practice, thus obviating this ground of objection.

For all of the foregoing reasons, reconsidering and withdrawal of the objections to the claims is respectfully requested.

**D. THE CLAIMS ARE PATENTABLE
SUBJECT MATTER UNDER 35 U.S.C. 101**

At page 4 of the Office Action, claims 1, 4 and 8-10 were rejected under 35 USC 101 as allegedly being directed to non-statutory subject matter. As suggested by the Examiner, claims 1 and 4 are amended to recite that the subject gene and DNA, respectively, is "isolated," thus obviating this ground of rejection. In addition, as suggested by the Examiner, claims 8-10 now recite an "[a]n isolated transformed cell..." thus obviating this ground of rejection.

For all of the foregoing reasons, reconsidering and withdrawal of the claim rejections under 35 U.S.C. 101 is respectfully requested.

**E. THE CLAIMS ARE DEFINITE
UNDER 35 U.S.C. 112, SECOND PARAGRAPH**

At page 5 of the Office Action, claims 1 and 4-17 were rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner has asserted that,

[c]laim 1 is indefinite in the recitation of 'stringent conditions' as the specification does not define what conditions constitute 'stringent'. While page 7 of the specification describes some conditions, which are intended to be stringent, there is nothing to suggest that other conditions would not also be included within the scope of this term and in the art what is considered stringent varies widely depending on the individual situation as well as the person making the determination.

The specific stringent conditions set forth in the specification are now recited by claims 1 and 17, thus obviating this ground of rejection of claims 1 and 17, and the claims dependent therefrom. Claim 4 has also been rejected for reciting "a base sequence...". Claim 4 is now amended to recite, "the nucleotide sequence..." thus obviating this ground of rejection.

For all of the foregoing reasons, reconsidering and withdrawal of the claim rejections under 35 U.S.C. 112, second paragraph, is respectfully requested.

**F. THE CLAIMS ARE ENABLED
UNDER 35 U.S.C. 112, FIRST PARAGRAPH**

At page 6 of the Office Action, claims 1, 5-6 and 8-17 were rejected under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter which was not described in the

specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner takes the position that,

These claims are directed to a genus of DNA molecules encoding any protein having chlorohydrin and hydroxycarboxylic ester asymmetric hydrolase activity from any source. The specification teaches the structure of only a single representative species of such DNAs. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of encoding a protein having chlorohydrin and hydroxycarboxylic ester asymmetric hydrolase activity.

Applicants respectfully disagree. Claim 1, is amended to more particularly set forth that which Applicants consider to be their invention. Claim 1 now recites an isolated gene comprising one of alternative nucleotides (a) - (e).

Nucleotide (a) corresponds to SEQ. ID. NO: 1.

Nucleotide (b) must be able to hybridize to SEQ. ID. NO: 1 under stringent conditions, as expressly defined.

Nucleotide (c) must encode an amino acid sequence described in SEQ. ID. NO: 2.

Nucleotide (d) must encode an amino acid sequence described in SEQ. ID. NO: 2 where one or a plural number of amino acid(s) is/are deleted, added or substituted from SEQ. ID. NO: 2.

Nucleotide (e) must encode an amino acid sequence described in SEQ. ID. NO: 2 wherein the encoded enzyme has 95% or more homology with the amino acid sequence described in SEQ. ID. NO: 2.

It is respectfully submitted that, contrary to the Examiner's assertion, the ordinary artisan, who has read the instant specification, will fully appreciate the metes and bounds of the claimed invention, and be able to reproduce the same.

For all of the foregoing reasons, reconsidering and withdrawal of the claim rejections under 35 U.S.C. 112, first paragraph, is respectfully requested.

**G. CLAIM 7 IS FULLY ENABLED
UNDER 35 U.S.C. 112, FIRST PARAGRAPH**

At page 10 of the Office Action, claim 7 was rejected under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner takes the position that in order for the plasmid of claim 7 to be fully enabled, a biological deposit must be made.

Applicants respectfully disagree. The requirement for a deposit of biological materials is respectfully urged to be reserved for those biological materials that cannot be specifically replicated by reference to the written description of the specification. In the present instance, the Examiner's attention is respectfully directed to Example 4 of the specification. In that example, it is submitted that specific, step-by-step instructions are given to preparing the DNA obtained in the foregoing examples for insertion into plasmid pKK223-3 (available from Pharmacia Co.) to obtain, *inter alia*, plasmid pKK-EnHCH1.

It is respectfully urged that nothing more is required, and that a patent deposit would be redundant in the present instance. For all of the foregoing reasons, reconsidering and withdrawal of the rejection of claim 7 under 35 U.S.C. 112, first paragraph, is respectfully requested.

G. THE CLAIMED INVENTION IS NOVEL UNDER 35 U.S.C. 102

At page 11 of the Office Action, claims 1, 5, 8-17 are rejected under 35 U.S.C. 102(b) as allegedly anticipated by Ohta et al. (US Patent 6,127,152). Ohta et al. (U.S. Patent 6,127,152) teaches the gene of hydroxylcarboxylic ester hydrolase and expression of this gene in *E. coli* JM109 and DHS α strains.

Applicants respectfully disagree. It is submitted that Ohta et al. discloses a gene encoding tricarboxylic acid ester hydrolase comprising 393 amino acids derived from *Burkholderia cepacia* (see column 2, lines 54-61 and Sequence Listing). In contrast, it is respectfully submitted that the invention of claim 1, *et seq.* is directed to an isolated gene having chlorohydrin and hydroxycarboxylic ester asymmetric hydrolase activity, which comprises 362 amino acids, that is derived from *Enterobacter sp.* as described on page 8, line 9 to page 9, line 6

of the present specification. According to the above, the gene of the present invention is different in origin, the number of amino acids and the enzyme substrate, from that of Ohta et al.

For all of the foregoing reasons, reconsidering and withdrawal of the claim rejections under 35 U.S.C. 102(b), is respectfully requested.

At page 12 of the Office Action, claims 1, 5, 8-13 and 17 rejected under 35 U.S.C. 102(a) as allegedly anticipated by Lee et al. (Appl Environ Microbiol, 2003, June 69, 3421-3426). Lee et al teaches a gene encoding an enzyme having hydroxycarboxylic ester asymmetric hydrolase activity and expression of this gene in *E. Coli*.

As discussed above, the Examiner has been provided with an English-language copy of the Japanese priority application. Based on perfection of the October 7, 2002 for the instant patent application, the Lee et al. reference, published in June of 2003, is not valid prior art under 35 U.S.C. 102(a).

Nevertheless, Applicants reserve the right to provide arguments distinguishing this reference if the Examiner, for some reason, maintains that Lee et al. is citable as alleged prior art under 35 U.S.C. 102(a).

For all of the foregoing reasons, withdrawal of the Lee et al. reference as alleged prior art under 35 U.S.C. 102(a), is respectfully requested.

H. THE CLAIMED INVENTION IS NOT OBVIOUS UNDER 35 U.S.C. 103(a)

At page 12 of the Office Action, claims 14-16 are alleged to be obvious under 35 U.S.C. 103(a) by any one of Pohlenz et. al. (US Pat.5543306) or Benton et al. (US Patent 6638718) in view of Lee et al. (Appl Environ Microbiol, 2003, June 69, 3421 -3426). Pohlenz et. al. (US Pat.5543306) and Benton et al. (US Patent 6638718) reported the expression of ester hydrolase gene in *E. Coli* JMI 09 strain and DH5 α strain.

As noted in part G of the response, *supra*, Lee et al. was published in June of 2003, and the present application is urged to be entitled to a priority date of October 7, 2002. With the removal of the Lee *et al.* reference, it is urged that the rejection under 35 U.S.C. 103(a) is incomplete and should be withdrawn.

Nevertheless, Applicants reserve the right to provide arguments distinguishing this reference if the Examiner, for some reason, maintains that Lee et al. is citable as alleged prior art under 35 U.S.C. 102(a) and 103(a).

For all of the foregoing reasons, withdrawal of the rejection under 35 U.S.C. 103(a) is respectfully requested.

I. CONCLUSION

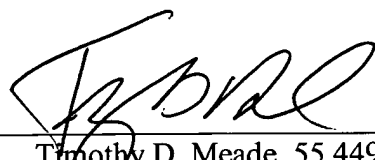
It is respectfully submitted that the present application is now in condition for allowance. An early and favorable action on the merits is earnestly solicited. If any questions remain, the Examiner is respectfully invited to telephone the undersigned.

No fee is believed to be due for this response. If it is determined that a fee is due, any deficiency or overpayment concerning this document should be charged or credited to Deposit Account No. 02-2275.

This response is filed together with a Petition for Extension of Time for Two Months, and the required Petition fee for a large entity. Nevertheless, should an additional petition for extension of time be required, please treat this document as the required petition and charge the required petition fee to the above-noted Deposit Account.

Respectfully submitted,

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